THIS PAPER IS FOR DISCUSSION AND DECISION **SC(20)141**

RESTRICTED HANDLING

SCOTTISH CABINET

INITIAL COVID-19 VACCINES DEPLOYMENT

PAPER BY CABINET SECRETARY FOR HEALTH AND SPORT

Purpose

1. Cabinet is invited to note the following update on the COVID-19 vaccines and agree the basis on which this will be deployed to all adults 18 and over across Scotland as a means to protect the most vulnerable and enable people to return to as normal life as possible.

Timing

2. The Joint Committee for Vaccinations and Immunisations (JCVI) provided an interim recommendation in September and will provide their final recommendations imminently. The Green Book chapter on COVID-19 vaccination was published on Friday last, and we expect the Medicines and Healthcare Products Regulatory Authority (MHRA) to provide an interim license for the Pfizer vaccine at the earliest on 30 November, with supplies being shipped at the earliest on 7 December. MHRA have also been asked to consider authorisation for the Oxford/AstraZeneca vaccine. Our intention and our planning is that vaccinations will commence as soon as they are received within NHS Boards. Agreement on our policy position will allow us to communicate this to NHS Boards via a CMO letter.

Background

3. The news of successful Phase 3 trials for COVID-19 vaccine candidates such as Pfizer and AstraZeneca offers hope, but as outlined within **Annex A**, there are at this stage a number of unquantified variables. We know the initial vaccines that are likely to receive an interim license will offer <u>some</u> protection, but we will not know how far a vaccine prevents severe disease or reduces transmission until after the vaccines are deployed. This will prove challenging to explain as many will assume that any vaccine will offer both of these. Notwithstanding this, given we know that any vaccine approved for use will offer some form of protection that we do not currently have, there is considerable value in ensuring this is delivered at scale and pace.

4. Whilst the vaccines are being secured through the UK Government on a four nations basis, it has been agreed that Scotland would receive 8.2% of the total supplies (minus a population-proportionate share for Crown Dependencies and overseas territories), which equates to the Barnett consequential formulae. As

noted, there are two vaccine candidates that are likely to receive a MHRA license and become available shortly. The table below outlines the anticipated delivery schedules and quantities we are expecting. However, these are subject to change and remain commercially sensitive information:

	Pfizer	Oxford
30/11/2020	165k	0
07/12/2020	165k	0
14/12/2020	83k	0
21/12/2020		165k
28/12/2020		165k
04/01/2021	165k	330k
11/01/2021	165k	330k
18/01/2021	165k	330k
25/01/2021	165k	330k

Developing a COVID-19 vaccines policy

5. The World Health Organisation (WHO) identifies vaccines as the second most important public health intervention behind clean water and sanitation. Vaccination touches on a number of intertwined human rights, including rights to life, to health and to personal choice. As outlined within Annex A, our policy response to national immunisation activity for all vaccines is guided by the JCVI who are the independent clinical body charged with providing recommendations to all Governments in the UK.

6. The objectives of the COVID immunisation programme is to protect those who are at most risk from serious illness or death. JCVI have set out a prioritisation for persons at risk, ranking the eligible groups according to their need, largely based on prevention of COVID-specific mortality and reduction in quality-adjusted life years. Evidence from the UK indicates that the risk of poorer outcomes from COVID-19 infection increases dramatically with age in both healthy adults and in adults with underlying health conditions. Those over the age of 65 years have by far the highest risk, and the risk increases with age. Older adults' resident in care homes have been disproportionately affected by the COVID-19 pandemic. JCVI has also considered other potential risk factors, including deprivation and ethnicity, and advised that any vaccination programme "*will need to ensure every effort is made to get good coverage in black, Asian and minority ethnic groups, in areas of higher socio-economic deprivation, and in areas with outbreaks or high levels of community transmission*".

7. The JCVI have therefore provided their interim recommendations, having reviewed the totality of the clinical data from the Pfizer Phase 3 trials and concluded the priority groups as set out below:

- older adults' resident in a care home and care home workers
- all those 80 years of age and over and health and social care workers
- all those 75 years of age and over
- all those 70 years of age and over
- all those 65 years of age and over
- high-risk adults under 65 years of age
- moderate-risk adults under 65 years of age

- all those 60 years of age and over
- all those 55 years of age and over
- all those 50 years of age and over
- rest of the population (priority to be determined).

8. Professor Wei Shen Lim, chair of JCVI has stated that the aim of vaccinating care home residents and staff, everyone over 50 in order of age in order from oldest to youngest and health care workers is to cover almost 99% of vaccine-preventable deaths from COVID-19.

9. While the Scottish Government is not compelled to follow JCVI advice (as England and Wales are so compelled), it has always done so. There are implications of adopting an age-based prioritisation model. Many sectors (and occupations) will consider themselves to be at increased risk and may therefore seek to be prioritised over others. Given the potential pressure that is likely to be applied, it will therefore be important that, should our policy position be to align with the JCVI advice, as would be usual, this approach is held consistently in Waves 1 and 2.

10. There is a strong desire and a sensible case for all nations in the UK to adopt a similar approach to this issue and all are therefore keen that we align our respective policy positions to the advice offered by JCVI. At the most recent four nations meeting of health Ministers on Thursday 26 November, it was agreed that all nations would adopt the same 'go live' date for delivering vaccinations, following the JCVI prioritisation advice. This would likely involve vaccinating those that will be delivering the vaccine on day 1.

11. Whilst the timeline and the prioritisation are dependent upon the approval and supply of vaccines, my officials have been working to comprehensively operationalise a nationally led, locally delivered vaccine delivery mechanism to ensure we are ready in anticipation of vaccines arriving, via the Flu Vaccinations and COVID-19 Vaccinations (FVCV) Programme Board.

Operational Preparedness

12. This is the largest and most complex logistical challenge we have faced and requires not only a substantial mobilisation within the NHS, but a whole public sector wide response. Both the Pfizer and the Oxford/AstraZeneca vaccines require two doses, four weeks apart. As you will see from the anticipated schedule of vaccines outlined within Annex A, this will not simply be a one-off event, but will likely require the delivery of multiple vaccines over the next 12 months and potentially require regular boosters in future years.

Operational challenges

13. The characteristics of the early vaccines are likely to prove challenging given that during a pandemic, vaccine manufacturers work on the basis that mass vaccination is the default option as a means to vaccinate as many people as possible, as quickly as possible.

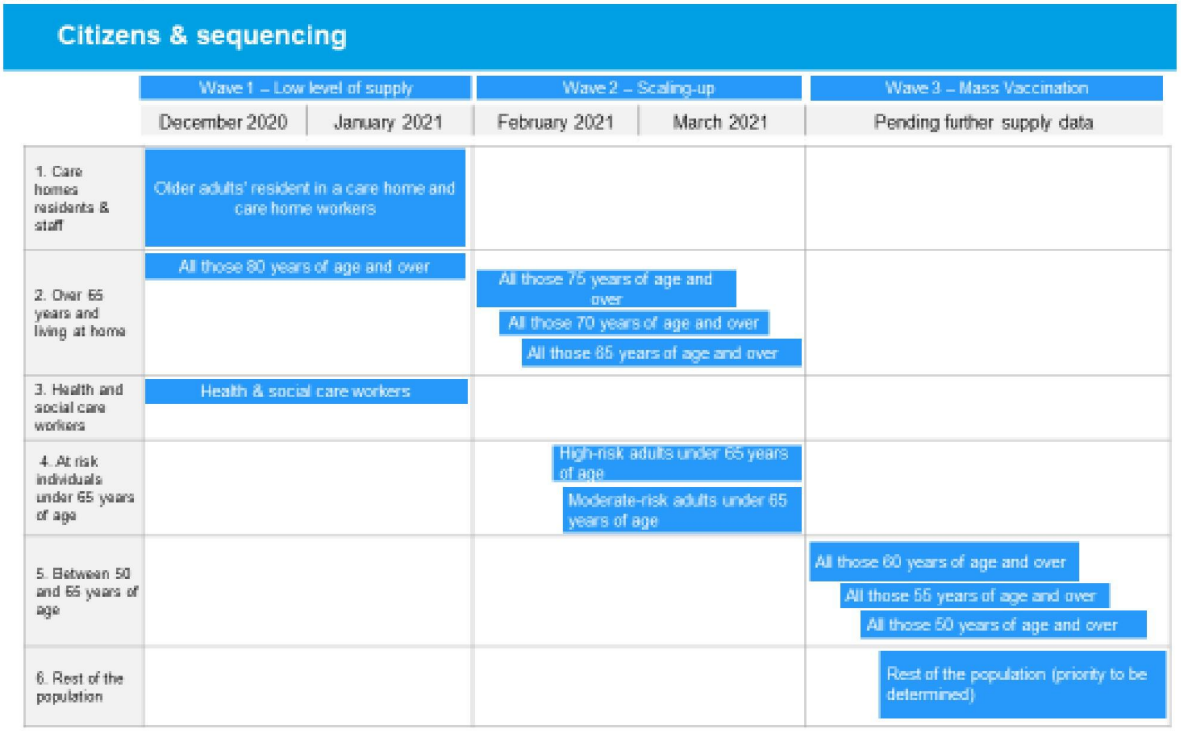
14. We know that the Pfizer vaccine needs to be stored at Ultra-Low Temperature and there are further constraints associated with the transport and administration of

this vaccine that bring additional challenges, the full details of which will only be confirmed this week following completion of a study of the vaccine's stability in transit post-thaw. Given these characteristics, we consider it unlikely we will be able to deliver it outwith mass vaccination centres. For many in the leading priority groups, we need to be able to take the vaccine to them or as close to them as possible, and mass vaccination centres will not be suitable. This means we need to have a range of vaccination locations (including mobile units) to meet this challenge, as well as the challenges of our geography. Fortunately, the AstraZeneca vaccine can be more easily transported. This vaccine could potentially be available from end December or early January, and may prove critical to vaccinating those who are unable to travel to mass vaccination centres.

15. In order to prepare, the FVCV Programme has developed a strategic delivery framework which has been used by the NHS Territorial Boards to act as the tramlines or framework within which they must plan delivery. This approach ensures there is consistency across the country, whilst allowing for some flexibility to meet local need and circumstances.

Planning and Phasing

16. The FVCV Programme has been working to establish a delivery infrastructure that would accommodate the interim priority groupings as set out by the JCVI. On that basis I have grouped delivery into three distinct waves based on clinical priority with those aged over 80 years old, those in care homes (both residents and staff) and health and social care workers forming Wave 1. The following summarises the three waves and the anticipated timeline based on current knowledge of delivery schedules:



This is an extract from the JCVI - Updated interim advice on priority groups for COVID-19 vaccination. This advice has been released to help boards to plan for the COVID-19 vaccination programme. The view on prioritisation will be refined when further information is available especially Phase 3 clinical trials information.

Work is in hand to ensure there is an effective invitation and recording system in place for each cohort. However, the soon to be confirmed details about the stability of the Pfizer vaccine in transit will be required to finalise our plans in relation to the arrangements for Care Homes and those aged 80 years and over living in the community either at home or for example, in sheltered housing.

17. Our FVCV Programme is working with all of the NHS Boards to scope out venues and options for the delivery of Waves 2 and 3, which include mass vaccination centres, community-based centres, deploying the wider Primary care community (dentists, GPs, community pharmacists), mobile units and drive through centres. My officials are being supported in this by the Army, but it is unlikely that the NHS alone can deliver this at the scale and pace we require. To that end, I am pleased that COSLA leaders have confirmed their support and work is in hand with Local Government and the third sector, to explore practical support that can be offered in all phases of the delivery model. However, even this may not be enough and we may need to consider how we deploy and repurpose the wider public sector and private sector e.g. venues, to ensure the population is vaccinated as quickly and safely as possible.

18. Given that the JCVI has not provided a recommendation of how to prioritise those aged 50 and under, I would propose to bring this matter back to Cabinet early next year.

Scaling up to meet the delivery challenge

19. As I set out during my Parliamentary statement, a National Delivery framework has been developed to inform NHS Board planning, and a readiness assessment is in hand.

Workforce

20. Changes to the Human Medicines Regulations 2012 to further enable the vaccine to be used with a temporary license, but also to allow a broader pool of individuals to administer vaccinations, mean NHS Boards will have flexible access to a wider pool of clinical resources, including the wider Primary Care clinical workforce later in Wave 1. What these changes mean in practice is that suitably trained healthcare support workers will be able to administer the vaccine in addition to the registered nurses and medics. Healthcare support workers will still need to be supervised by registered staff, and registered staff will still be essential to obtaining consent from vaccinees.

21. We have provided a national workforce modelling tool to health boards that is capable of being altered locally according to particular vaccination cohorts and relevant delivery timeframes. We intend to keep this tool live throughout the programme and to update it in accordance with actual delivery data from each wave. For Wave 1, current modelling assumptions estimate that we will require a total workforce of over 2000 WTE (vaccinators and support staff) with a COVID-19 vaccinator workforce of c. 1300 WTE by the end of January, growing progressively from around 530 WTE in December. (For reference, at peak, the extended flu WTE vaccinator workforce was c. 911 WTE).

22. We have already mined the Accelerated Recruitment Portal for qualified vaccinators and boards are taking forward recruitment processes with c. 147 individuals. We have also identified up to 1,000 staff in the portal who may be suitable to support the vaccinations programme, either as vaccinators or administrative staff; boards have been provided with lists of all staff remaining in the portal who live in their board area, and are instructed to consider each individual with a view to appointing as many as possible. Additionally, the Chief Medical and Chief Nursing Officers have written to the keepers of the emergency registers and officials are working proactively with boards to identify further suitable persons.

23. The Army, local government and community planning partners are assisting with logistical and non-clinical delivery support, including staff, venues and transport to and from vaccination centres. We fully anticipate however that for Waves 2, 3 and beyond, not only will the programme require the continuing mobilisation of staff across the public sector, but that boards will need to build progressively a larger and more sustainable vaccinator workforce over the course of 2021 to enable us to take forward cyclically any repeat or booster Covid vaccination, alongside the seasonal flu programme.

Stock Management

24. Tracking and cold storage management of vaccine stock is in hand and agreements have been reached on the future distribution and supply of vaccine to each Health Board. A key consideration underpinning this activity is to facilitate effective and efficient use of the vaccine stocks that become available to us while ensuring delivery is person-centred and reflects local needs, offering the priority groups coming forward the information and support they need to access vaccination in an equitable way.

Digital infrastructure to support delivery

25. There is currently no single national digital infrastructure in place to record vaccinations. Therefore a Vaccination Management Tool has been developed which will collect data on vaccinations at point of vaccination in all settings outwith GP surgeries, and will inform national reporting systems, acting as the single source of management information to both NHS Boards and Scottish Government. The individual's CHI number will be recorded at the point of vaccination which will allow links to be made across their medical records. This is critical for both the current vaccination programme but also in the event that future COVID-19 vaccines need to be deployed. Through the CHI linkage we will be able to provide information on vaccination to GP IT systems, and to NHS24.

26. Whilst this work has been delivered at pace in preparation for the delivery of a COVID-19 vaccine, I have been mindful that this represents an opportunity to deliver a positive legacy for Immunisation in Scotland as this system can be used for all vaccinations. This will therefore contribute towards our commitment in the Programme for Government to the delivery of a world class public health system.

Communications

27. How we engage and explain the vaccination programme will be critical to its success given these will be new vaccines and despite them being safe, they have never been deployed at population level before. My officials have therefore developed a communications plan that takes account of both vaccine hesitancy and the more extreme anti-vax movement.

28. A National Call Centre is being established to provide information about the vaccine and the vaccination process. Communications will include national, local and sectoral messaging produced and disseminated in accessible formats and in a range of community languages, and designed to promote vaccine safety and address vaccine hesitancy, and to positively and consistently counter anti-vaccination sentiment, engaging with community groups and community leaders to encourage people from minority ethnic and other communities who might be less likely to attend for vaccination.

29. We shall also develop national campaigns using existing channels and I would propose to undertake a household door drop in early 2021 to both highlight the importance of being vaccinated and explain how the programme is being delivered.

Legislation

30. Following the amendments to the Human Medicines Regulations 2012, officials are drafting a protocol, to be approved by Scottish Ministers, which will set out the wider pool of people who can administer vaccinations, informed by clinical views.

31. To minimise the risk of waste given the large pack size (195 vials representing 975 doses) and limited stability (5 days at +2-8°C), it is planned that when the vaccine is to be used, the required doses will be taken out of the ultra-low temperature freezer and packed-down in hospital pharmacy departments into a smaller pack size under Section 10 of the Medicines Act 1968. Where feasible, the packing down will be undertaken at +2-8°C in a cold room. A small number of locations do not have capacity in their cold room to undertake this activity; in these instances, the vaccine will be packed down whilst thawing and then placed as quickly as possible into a fridge at +2-8°C. We are awaiting confirmation from the MHRA that our proposal is acceptable.

32. A packaging solution has been identified and tested to ensure that the vials can be held securely in transit. The Scottish Pharmacy Quality Assurance Group (Scotland's network of quality assurance pharmacists) is in the late stages of developing a national template protocol for retrieval of the vaccines from freezers, packing and labelling the container for onward storage and distribution. Subject to the company providing the necessary stability data, the vaccine will then be transferred from vaccine holding centres to vaccination administration sites.

Parliamentary Handling

33. Effective communications will be critical in explaining the rationale for any approach and in order to achieve a high level of uptake. I have already made an

initial statement to Parliament but plans are in hand to update Parliament on a regular basis as the vaccine arrives and to ensure individual MSPs have the information they need for their area.

Finance

34. As part of the UK Government's Spending Review announcement on 26 November, HM Treasury provided a clearer reconciliation of Covid-19 consequentials for 2020-21, as well as setting out funding proposals for 2021-22. Following confirmation of this position, I recognise that the Cabinet Secretary for Finance is considering how best to manage both the in-year financial position and next year's financial plans across the total Scottish Government budget.

35. Although the cost of the vaccines are not being borne by the Scottish Government, the delivery costs are. Therefore, given the central role the vaccination programme has in us tackling the pandemic, I would however stress that it is absolutely critical that funding is made available as a priority and allocated appropriately to support this work. In the first instance, I would want to target some of the health related Covid consequentials, which were confirmed through the HM Treasury reconciliation process, to support the vaccination deployment and delivery support.

36. In terms of costs, I expect to be in position to provide an initial assessment for the programme costs by the middle of December. As planning assumptions and associated policy guidance are now being made available to Health Boards (e.g. priority groups, delivery schedules, technologies and workforce), my officials are working closely with NHS Boards and will be assessing estimated costs over the coming weeks.

Conclusion

37. **Cabinet is invited to**:

(a) **Agree that the Scottish Government's policy position should be aligned to the final JCVI recommendation, recognising that those at the highest clinical risk should receive the vaccine first**;

(b) **Note the work in hand to operationalise delivery**;

(c) **Support the mobilisation activity required to scale up within Waves 2 and 3, by considering how each Portfolio can provide resources drawn from the wider Public Sector to augment delivery**; and

(d) Engage with their stakeholders to manage the pressure that will undoubtedly be applied seeking exemption from the JCVI prioritisation exercise.

JF
November 2020

ANNEX A

INITIAL COVID-19 VACCINES DEPLOYMENT

BACKGROUND

Role of Immunisation to protect public health

The World Health Organization (WHO) identifies vaccines as the second most important public health intervention behind clean water and sanitation. Globally, there are vaccines to prevent more than 20 life-threatening diseases, and immunization currently prevents 2 to 3 million deaths every year from diseases like diphtheria, tetanus, pertussis, influenza and measles. However, vaccine hesitancy now ranks alongside antimicrobial resistance and climate change in the top 10 global health threats, according to the World Health Organization.

Vaccines work by inducing a natural infection to stimulate an immune response, but without causing disease. Most of the vaccines we use already stimulate the production of antibodies that bind to the virus, eliminating the infection. Most COVID-19 vaccines under development aim to stimulate an effective immune response to one component of the virus, the outer viral spike or S protein, whilst minimising the risks of adverse effects to the immune system. Once shown to be safe, the ideal vaccine:

- stimulates immune responses that reduce both the risk or the severity of disease and the chance of transmission of the infection; and
- gives long-term protection so people do not need to be frequently re-vaccinated.

Few vaccines meet all these standards. COVID-19 vaccines in development are unlikely to result in complete protection against infection in all recipients. The World Health Organisation has given a Target Product Profile for a COVID-19 vaccine as inducing a minimum of 6 months but preferably at least a year of protection, with efficacy in at least 50% of the population (preferably 70%) including in older people.

How a vaccine works is referred to as vaccine efficacy. Some vaccines prevent disease, some also prevent infections, and the impact on virus transmission is also an important component in assessing efficacy. Phase 3 trials help us understand how a vaccine affects symptomatic infections. But the next phase, as the vaccine is deployed, will gradually allow researchers to gather more information on how far a vaccine prevents severe disease or reduces transmission.

Scotland's track record in delivering vaccination programmes

In Scotland, infectious diseases were the major cause of death in the period after the First World War. The great influenza pandemic of 1918-19, is estimated to have caused 17,575 deaths in Scotland. In the 1920s, there were severe outbreaks of measles and whooping cough with substantial loss of life. Today, immunisation is a highly successful public health intervention that protects individuals and communities from serious infectious diseases, saving many lives each year. Uptake of the over 65s flu vaccination is consistent at 74% in recent years, and over 93% of children are vaccinated for MMR by 6 years. Uptake of vaccines in Scotland is generally high,

however it is lower in deprived areas, and among certain ethnic minority groups, which is why we invest heavily in communications tailored to these groups. In Scotland, there is a high level of confidence in vaccination programmes, with the vast majority of children receiving their booster vaccinations by 24 months and around 75% of over 65 year olds choosing to be vaccinated annually against flu.

COVID-19 vaccines in development

There are over 200 vaccines in various stages of development. Each vaccine is subject to clinical trials. Phase 1 is an initial trial to make sure that the vaccine is safe for humans and to work out the most effective dose. Phase II trials assesses consistency and identifies the ability to generate an immune response, whilst monitoring any potential side effects. Phase III gather statistically significant data on the vaccine's safety and efficacy (how well it works). This includes assessing whether the vaccine generates a level of immunity that would prevent disease, and provides evidence that the vaccine can actually reduce the number of cases. It also gives a better chance of identifying rarer side effects not seen in the phase II study. Trial data is then shared with regulators to test the safety and effectiveness of each vaccine. It is only when a clinical trial reports that we know if a vaccine is safe for deployment, and the degree to which it protects those who are vaccinated. There are 10 COVID-19 vaccines in Phase 3 clinical trials at the moment, with the first of these (the Pfizer vaccine) due imminently, with the Oxford/AstraZeneca due shortly after. The UK has secured early access to over 355 million vaccines doses through agreements with several separate vaccine developers at various stages of trials:

- 100 million doses of University of Oxford/AstraZeneca vaccine – phase 3 clinical trials
- 40 million doses of BioNTech/Pfizer vaccine – phase 3 clinical trials
- 5 million doses of Moderna vaccine – phase 3 clinical trials
- 60 million doses of Novavax vaccine – phase 3 clinical trials
- 60 million doses of Valneva vaccine – pre-clinical trials
- 60 million doses of GSK/Sanofi Pasteur vaccine – phase 1 clinical trials
- 30 million doses of Janssen vaccine – phase 3 clinical trials

Pfizer/BioNTech and Oxford/AstraZeneca Vaccines

Vaccines' efficacy

Efficacy of the vaccines is not yet fully understood. At this stage we have the reported efficacy from the Phase 3 trials, which will require review by regulatory and advisory bodies. For Pfizer this is 90% (and 94% for over 65 year olds), but this equates to an assessment of the total number of people presenting with COVID-19 symptoms and consequently being tested positive for COVID-19 with 10% of these having received the vaccine. This does not therefore provide an overall efficacy as Phase 3 trials do not assess asymptomatic infection, nor whether the virus continues to shed (for either symptomatic or asymptomatic patients). The same qualifiers apply to AstraZeneca's Phase 3 interim results, showing it to be 70.4% effective.

We understand that Human Challenge Trials are likely to commence in the UK early next year. These trials will assess impact on transmission by providing candidates with a vaccine and then exposing them to the virus.

On this basis, any approach to methods of demonstrating or 'proving' that someone has been vaccinated (often referred to as 'immunisation certificates' or 'vaccine passports') would not be appropriate as it is not yet clear exactly how much or whether it reduces the risk of transmission.

Vaccines' characteristics

We know that the Pfizer vaccine presents particular storage and transportation challenges given the vaccine needs to be stored at -70 degrees Celsius (plus or minus 15 degrees) and is only viable for five days at fridge temperature. At this stage we are awaiting stability data which will inform delivery decisions on whether the vaccine can be transported beyond the Ultra-Low Temperature storage requirement. We anticipate receiving that data during week commencing 30 November.

We have provided Health Boards with ultra-low temperature freezers and these are being validated before use according to a nationally agreed protocol. All Health Boards are reporting that they will be in a position to receive the vaccine by the end of November. As an assurance measure, the Director of Pharmacy in each Health Board is being asked to complete a checklist by 30 November to confirm installation qualification, operational qualification and performance qualification of the equipment. In addition, they are being asked to confirm that a risk assessment and appropriate safety equipment is in place to support receiving shipments containing dry-ice and handling the vaccine at ultra-low temperatures.

The vaccine will be supplied at -75°C±15°C from the Pfizer packaging site (Peurs, Belgium) to Movianto (Haydock) in Pfizer's thermal shipper. It will then be delivered by Movianto to the 22 Health Board vaccine holding centres at -75°C±15°C in Movianto's thermal shipper; this step of the supply chain is managed by Public Health England under their storage and distribution contract with Movianto. On receipt at a Health Board vaccine holding centre, it will be taken out of the thermal shipper and the tray of vaccines will be placed within an ultra-low temperature freezer at -75°C±15°C where it will remain until required.

The AstraZeneca vaccine can be more easily administered in existing healthcare systems, stored at 'fridge temperature' (2-8 °C) and distributed using existing logistics.

A table setting out the characteristics of the Pfizer and AstraZeneca vaccines is at **Annex B**.

Vaccines' Supply

We have been working with the Department for Business, Energy and Industrial Strategy and the Department for Health and Social Care and agreed that COVID-19 vaccines should be secured on a UK wide basis, as this gives us both security of supply and enables greater purchasing power when placing orders.

To that end, there are now seven contracts in place with additional early stage developments in consideration and we are carefully monitoring data being received on a weekly basis on the potential delivery schedules. The contracts in place would deliver substantially more vaccines than would be required, amounting to 355m

doses, on the basis that some may be more effective than others and some of these may not successfully complete phase 3 trials.

Independent Clinical Advice: Role of JCVI and MHRA
Immunisation policy in Scotland is set by the Scottish Government on the advice of the JCVI and other appropriate bodies. The JCVI:

- assesses evidence and makes recommendations for all immunisation programmes;
- advises the UK Government and the NHS in the four nations about all aspects of immunisation; and
- supports implementation of all immunisation programmes.

Before a vaccine is put into general use it has to be licensed through the MHRA. In order to be granted a licence, the manufacturers have to demonstrate its quality, safety and efficacy in preventing the particular disease for which it's intended. Once introduced, vaccines are constantly monitored so that any new side effects are quickly noticed and investigated.

The MHRA monitors the safety of licensed vaccines through the Yellow Card Scheme. The information collected through the Scheme is constantly reviewed by independent experts and used to inform national immunisation policy decisions.

JCVI Recommendations
The JCVI has issued interim advice to support planning for the deployment of any safe and effective vaccine as soon as they are authorised by the MHRA for use in the UK. Evidence from Phase 3 trials regarding vaccine safety and effectiveness will decide whether and how any vaccines will be used in the UK.

The JCVI has found that the risk of serious disease and death of COVID-19 increases exponentially with age and is also increased in those with a number of underlying health conditions. It has advised that as long as an available vaccine is both safe and effective in older adults, they should be a high priority for vaccination. An age-based programme is also likely to capture those with clinical risk factors as the risk of death is very strongly linked with age, more so than any other factor. The committee's updated interim advice sets this out:

- older adults resident in a care home and care home workers
- all those 80 years of age and over and health and social care workers
- all those 75 years of age and over
- all those 70 years of age and over
- all those 65 years of age and over
- high-risk adults under 65 years of age
- moderate-risk adults under 65 years of age
- all those 60 years of age and over
- all those 55 years of age and over
- all those 50 years of age and over
- rest of the population (priority to be determined).

While it is not in the public domain, we understand that the initial group will be widened to include all adults resident in a care home, and that the top three priority groups will be presented together to allow for operational discretion. As we understand more about the clinical characteristics of a vaccine, we will then consider the merits and prioritisation of vaccinating lower risk adults in the UK. **Annex C** sets out the number of people who will be eligible for vaccination in Scotland.

We have prepared well for this programme, and we expect to receive enough vaccine doses for everyone in due course. But that supply will be staggered, and is dependent on a range of vaccines, all of which will need to go through the necessary trials, safety and efficacy checks and approval process.

Sectoral Prioritisation

While the Scottish Government is not compelled to follow JCVI advice (As England and Wales are so compelled), it has always done so. The JCVI provides expert advice formed by reviewing the clinical and scientific evidence. However there are implications of adopting an age-based prioritisation model. It is already clear that many sectors (and occupations) will consider themselves to be at increased risk and may therefore seek to be prioritised over others – calls have already been received from the teaching profession, for example, who argue that this would reflect the Scottish Government's priority of keeping schools open safely, and similar approaches have been received from the Police Federation, Scottish Prison Officers, essential workers in critical national infrastructure and ethnic minority groups). This is pertinent as the JCVI advice has not proposed further prioritisation other than for those aged 50 or under. Given the potential pressure that is likely to be applied, it will therefore be important that, should our policy position be to align with the JCVI advice as would be usual, this approach is held.

Operational implications

Planning

A strategic Delivery Framework has been developed which sets out in detail how we plan to deliver Scotland's first mass vaccination programme in many years.
Delivery will be guided by the following principles:

- Person centred
- Safe
- Effective
- Efficient
- Equitable
- Timely
- Local.

From the start of the process, we have carried out impact assessments to ensure that the interests and needs of the whole population are taken into consideration in the design of the Programme. The delivery of the vaccination programme should be built around a human rights PANEL approach (Participation, Accountability, Non-Discrimination and Equality, Empowerment and Legality), and this is reflected in the various workstreams of the FVCV Programme Board covering vaccine safety and confidence, informed consent, inclusive communications, and person-centred

delivery. No matter how, when or where a person presents for vaccination, they should experience the same high standard of person-centred care, which uses the resources we have in the most efficient and effective way.

Programme Management and oversight

A National Delivery framework has been developed to inform NHS Board planning, initial plans have been submitted and feedback provided. We have also issued a readiness assessment and are supporting NHS Boards with daily calls to complete this and to improve their readiness to commence vaccination.

Given the scrutiny the vaccination programme will come under, considerable work has been undertaken to ensure there is an accurate and timely flow of management information. To that end Key Performance Indicators and information flows for reporting have been developed and will be communicated to NHS Boards. The data flows from the VMT to national reporting systems have been successfully tested and this will be the single source of management information to both NHS Boards and Scottish Government.

National and Board-level Communications

Work is well progressed in developing a national communications plan, which is in the process of being submitted to Ministers for approval. This will include both national activity (mail drops, media campaigns etc.) but also tools that can be deployed by NHS Boards and other. These include a toolkit for Boards to use for HSPs; influencer & stakeholder material and Q&A; and updating the NHS inform material and directory.

National engagement with sectoral groups is well underway, with plans to tailor inclusive communications and enable effective peer communication.

Communications have been designed and tested to address vaccine hesitancy, and to positively and consistently counter anti-vaccination sentiment. UK Government is engaged in proactive social media monitoring of anti-vaccination messaging.

Managing invitations and appointments

A Vaccination Management Tool (VMT) has been developed and has been successfully trialled in several flu clinics. NHS Boards have been advised that they are require to use the VMT to collect data on vaccinations at point of vaccination in all settings outwith GP (where GPIT will continue to be used). Work is also underway to provide NHS Boards with national cohorts for checking. We have provided advice on the definition of frontline health and social care workers, and will communicate this to Boards to ensure consistency of approach as soon as this has been approved.

A National Call centre is being established and resourced to take the pressure off local Health Boards (or GP surgeries etc.). Initially this will be used to provide information about the vaccine and the vaccination process rather than manage any invitation or booking system.

Clinical workforce

NHS Boards will have access to a wider pool of clinical resources with DES being developed to enable involvement of GP practices and the wider Primary Care clinical workforce from Wave 1. Work has also accelerated on the development of a National Protocol and PGD (Patient Group Directive) in anticipation of the JCVI and MHRA decision.

NHS Education for Scotland and Public Health Scotland are developing a suite of workforce education resources for registered and non-registered staff groups specific to COVID-19 vaccines as soon as JCVI, MHRA and associated final Green Book chapter details are finalised) to be offered through various media, including large scale webinars. This will enable vaccinators to feel confident in discussing the vaccines characteristics with those that they will vaccinate, understand any consent or legal issues and safely administer the vaccine in line with the product-specific characteristics.

Non-clinical workforce

COSLA, SOLACE and the local resilience partnerships are involved in developing logistical and non-clinical delivery support, including staff, venues and transport to and from vaccination centres. Third sector input to support and promote vaccination at a local level is being developed, and support from the Army on logistics and planning is underway.

Clinical governance

Work has been undertaken to develop an Adverse Event standard Operating Procedure, to ensure there is a consistency in approach from a clinical perspective and sets out the necessary clinical governance for the programme.

A surveillance model will commence when vaccinations begin to provide clinical analytical data on the impact of the programme.

Vaccines logistics (inc cold storage)

There will be a digital solution for the tracking and management of vaccines stock for wave 2 onwards, but for Wave 1, we have put in place arrangements to build on the systems in place within NSS and NHS Boards. Arrangements have also been made and shared with NHS Boards on their initial allocations of vaccines based on our understanding of the delivery dates as they stand. We have also confirmed there is sufficient cold storage for receipt of the vaccines for wave 1. Furthermore, agreements have been reached on the future distribution and supply of vaccines to each Health Board.

Legislative requirements

All of the necessary legislative and regulatory requirements have been developed at pace, including changes to the Human Medicines Regulations 2012 to enable both the vaccine to be used with a temporary license, but also a broader pool of individuals to undertake the vaccination.

Assessing the Impact of vaccination

Ongoing clinical trials to understand efficacy

Successful vaccines will play an important part in our efforts to return to a more normal life for as many people as possible, alongside testing and new treatments. As vaccines are deployed, monitoring will continue to see how it affects transmission of the disease. The Human Challenge Trials likely to commence in the UK early next year, will assess impact on transmission by providing candidates with a vaccine and then exposing them to the virus. On this basis, any approach to methods of demonstrating or 'proving' that someone has been vaccinated (often referred to as 'immunisation certificates' or 'vaccine passports') would not be appropriate as it is not yet clear exactly how much or whether it reduces the risk of transmission.

Focus on interaction between vaccination, testing and NPIs

The critical interaction between vaccination, testing, and other non-pharmaceutical interventions (NPIs) like the current restrictions and FACTS will become the focus of clinical, analytical and policy consideration in the coming months. The aim will be to assess the extent to which vaccinations and testing (separately and together) mitigate the risk of the virus and allow for the relaxing of restrictions. Over time, it is hoped that testing and vaccination will reduce transmission, which will show up in the five levels indicators, allowing local authorities to move down the scale.

The vaccination roll out will be incorporated into the modelling undertaken on the Covid-19 epidemic in Scotland. Modellers will attempt to model the vaccination effect on the number of infections, hospitalisations (including ICU) and deaths over 2021. It will however be some time before the effects of the vaccine programme will be able to be reflected in R, growth rates etc. Understanding the vaccination programme's effect e.g. around take up and transmission, is crucial and will be a central part of the modelling work undertaken next year.

Effective communications to drive uptake

Alongside this, there needs to be sustained effort on communications and marketing in relation to take-up of vaccinations and testing, as well as continued compliance with restrictions. Our planning assumption is 75% uptake – this is a stretching target. At this stage it is not possible to assess the level of immunity that would be required to reduce or prevent transmission to those that do not have the vaccine. This is often referred to as herd immunity. It will therefore be important to deploy vaccines as one part of the toolkit as it provides better protection than any other measure that we have, but it is unlikely to be a panacea. Professor Wei Shen Lim, chair of JCVI has stated that the aim of Phase 1 of the programme is to cover almost 99% of vaccine-preventable deaths from COVID-19.

Ongoing assurance of vaccines supply

In 2021, we will work to ensure that a steady stream of safe and effective vaccine doses are secured for use in Scotland. The UK Government has purchased vaccines for each of the four nations in this early stage of development, and we will explore future options for procurement, including purchasing our own supplies, as we already do with some other vaccines.

Planning for Wave 3 and beyond

We will also consider the future of the vaccination programme in light of epidemiology, emerging findings around the likely benefits of vaccinating children and young people and the need to boost vaccination over time.

During this time, it is crucial that vaccine trials continue, and people continue to volunteer to provide access to a wider range and increased supply of approved vaccines and to inform clinical advice about their deployment. We will also take steps to encourage the universities and businesses across the country already working on a number of critical COVID-19 treatments and research projects, looking to our life sciences community to continue to support our response to COVID-19 and help shape our economic recovery.

The urgent, complex and important work in planning for a mass COVID-19 vaccination programme has built on the work begun by the Vaccine Transformation Programme in 2018. We will make time to reflect and evaluate as we go, learning lessons and applying them quickly and effectively, so that all our vaccination programmes contribute to our goal of a world class public health system in Scotland.

ANNEX B

INITIAL COVID-19 VACCINES DEPLOYMENT
SUMMARY OF LEADING COVID-19 VACCINE CHARACTERISTICS

	Pfizer BioNTech	Oxford AstraZeneca
Qualitative and quantitative composition	mRNA technology	Recombinant technology
Therapeutic indications	For the prevention of COVID-19 for adults 16y+.	For the prevention of COVID-19 for adults 18y+.
How long should people be monitored post-administration?	Patients should be observed for 30 minutes after vaccination.	no observation is required
Interaction with other medicinal products and other forms of interaction	No combination with other vaccines	TBC by supplier
Pregnancy and lactation	Not available to those that are pregnant	Not available to those that are pregnant
Effects on ability to drive and use machines	Patients should be observed for 30 minutes after vaccination.	No effects evident
Undesirable effects	Adverse reactions that have been reported for the Pfizer BioNTech COVID-19 Vaccine are injection site pain, fever, chills, fatigue, muscle pain, and headache. Adverse reactions associated with the vaccine, some of which may be serious, may become apparent with more widespread use.	TBC by supplier
Shelf life	Store at label claim up to expiry, at -75°C±15°C for storage up to 6 months)	Current shelf life is 6 month stored at 2-8C

	Pfizer BioNTech	Oxford AstraZeneca
Special precautions for storage	Vaccine is stable for 5 days in a fridge before reconstitution and for 6 hours at room temperature after reconstitution. Vaccine Storage - ULT Freezer - Store at label claim up to expiry. (at -75°C±15°C for storage up to 6 months) - Thermal shipper designed for temporary storage - 5 days with replenishment of locally sourced dry ice with 2 openings/day. - Multiple dry ice replenishments possible. Up to 15 days (3 times re-icing). - 2-8°C refrigerator - 5 days at 2-8°C storage	Recommended that the vials are stored in the cartons, away from direct sunlight to prevent prolonged light exposure and kept upright. -Unopened vials must be stored at 2°C to 8°C for the duration of assigned shelf-life. - must not be frozen. - must be kept in original packaging until use to prevent prolonged light exposure. - each vial must be assigned a beyond-use-date of 4 hours from first needle puncture of the vial, after which any unused portion must be discarded. - once a dose is drawn into a syringe for administration, the dose must be administered within the beyond-use-date of the vial. - if the AZD1222 dose administration is not completed within the 4 hour vial beyond-use-date, a new dose must be prepared from a new vial. - the product must be stored upright at all times.
Contains products of animal origin (including materials are derived from embryos or foetuses) / cell culture media uses animal derived products	All materials are of non-human/non-animal origin	Process uses porcine derived material at a very early stage in the process. Animal based material is subsequently eliminated by multiple washing and by ultrafiltration.
Shelf life on delivery	Store at label claim up to expiry (at -75°C±15°C for storage up to 6 months)	6 months from point of vial fill. Days 40-45 then needed for vial testing and release. Needs to be stored away from direct sunlight.

	Pfizer BioNTech	Oxford AstraZeneca
Administration	Diluted product must be used within 6 hours at room temperature. Administer intramuscularly as a series of two doses. A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.	Administer intramuscularly as a series of two doses.
Schedule of Doses	2 doses, interval of 21 days	2 doses per person, interval of 28 days JCVI could potentially recommend giving 1 dose to the wider general public initially
Is diluent required?	Yes	No
Doses per vial	Each vial contains 5 doses	5 ml vials (8 dose fill); IDT: 6 ml vials (10 dose fill) Each vial has a label-claim volume of 5 mL and can provide up to ten 0.5 mL doses.
Other consumables required for administration	Other PPE and ancillary materials needed for vaccination centres such as alcohol wipes, gloves etc.	No

ANNEX C

JCVI Priority	Cohort	Cohort Description/Definition	Approx Cohort Size
1	Care home residents	Residents of older adult care homes	32,000
1	Care home staff	The staff that work in care home settings	53,500
2	Over 80s	Those aged over 80 living in the community	260,000
2	Health care workers	All frontline healthcare staff who are eligible for seasonal influenza vaccination should be offered COVID-19 vaccine. This includes the following groups. **Staff involved in direct patient care** - This includes staff who have frequent face-to-face clinical contact with patients and who are directly involved in patient care in either secondary or primary care/community settings. This includes doctors, dentists, midwives and nurses, paramedics and ambulance drivers, pharmacists, optometrists, occupational therapists, physiotherapists and radiographers. Students and trainees in these disciplines and volunteers who are working with patients must also be included. **Non-clinical staff in secondary or primary care/community healthcare settings** - This includes non-clinical ancillary staff who may have social contact with patients but are not directly involved in patient care. This group includes receptionists, ward clerks, porters and cleaners. **Laboratory and pathology staff** - This includes laboratory and other staff (including mortuary staff) who frequently handle SARS-CoV-2 or collect or handle potentially infected specimens, including respiratory, gastrointestinal and blood specimens. In addition to technical staff, this may include cleaners, porters, secretaries and receptionists in laboratories. Staff working in academic or commercial research laboratories who handle clinical specimens or potentially infected samples should also be included.	180,000
2	Social care workers	This would include: - Those working in long-stay residential and	110,000

JCVI Priority	Cohort	Cohort Description/Definition	Approx Cohort Size
		nursing care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality - Social care staff directly involved in the care of their patients or clients - Others involved directly in delivering social care such that they and vulnerable patients/ clients are at increased risk of exposure	
	Unpaid carers	Significant overlap with age-related cohorts	750,000
3	75-79	Number shown includes Care Home residents so will be slightly less	195,951
4	70-74	Number shown includes Care Home residents so will be slightly less	278,856
5	65-69	Number shown includes Care Home residents so will be slightly less	299,444
6	High risk under 65	All those between 18 and 64 years of age and have a condition which makes them clinically extremely vulnerable.	77,800
7	Moderate risk under 65	All those between 18 and 64 years of age and have a condition which makes them clinically vulnerable	800,000
8	60-64	Currently includes H&SC workers and risk groups above – these require to be discounted	344,693
9	55-59	Currently includes H&SC workers and risk groups above – these require to be discounted	393,123
10	50-54	Currently includes H&SC workers and risk groups above – these require to be discounted	401,090
11	18-49s	Currently includes H&SC workers and risk groups above – these require to be discounted	2,251,087